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DEPARTMENT OF HEALTH AND HUMAN SERVICES

CFN:1124028
Facility ID:110957
Inspection ID #1109570011

Food and Drug Administration
Baltimore District Office
900 Madison Avenue
Baltimore, MD 21201-2199
Telephone: (410) 962-3396

01-BLT-44

September 24, 2001

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ellen Richardson, Mammography Supervisor
Drs. Wityk, Goad, Korangy and Associates
724 Maiden Choice Lane
Suite 102
Baltimore, Maryland 21228

Dear Ms. Richardson:

A representative from the State of Maryland under contract to the Food and Drug Administration (FDA) inspected your facility on September 12, 2001. This inspection revealed a serious regulatory problem involving mammography performed at your facility.

Under a United States Federal law, the Mammography Quality Standards Act (MQSA) of 1992, your facility must meet specific requirements for mammography. These requirements help protect the public health by assuring that a facility can perform quality mammography. The inspection revealed the following Level 1 findings:

- **Your facility processed mammograms when your mammography processor was out of limits on at least five days during the 12 months proceeding the date of your inspection.**

- **Your facility failed to document that processor quality control was performed for at least five consecutive days in the month of February 2001.**

The specific problems noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection. These problems are identified as Level 1 findings because they identify a failure to comply with a significant MQSA requirement.

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography performed at your facility, they represent a violation of the law that may result in FDA taking regulatory action without further notice to you.

These actions include, but are not limited to: placing your facility under a Directed Plan of Correction; charging your facility for the cost of on-site monitoring; assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with MQSA

standards; suspension or revocation of your facility's FDA certificate; or obtaining a court injunction against further mammography.

In addition, the following Level 2 findings were listed on the inspection report provided to you at the close of the inspection:

- **Your facility failed to produce documents verifying that the medical physicist [redacted] met the continuing education requirement of having taught or completed at least 15 continuing education units in mammography in 36 months.**

- **Your facility failed to produce documents verifying that the medical physicis[redacted] met the continuing experience requirement of having surveyed at least 2 mammography facilities and a total of at least 6 mammography units in 24 months.**

It is necessary for you to act on this matter immediately. Please explain to this office in writing within fifteen (15) working days from the date you receive this letter:

- The specific steps you have taken to correct the violations noted in this letter; and

- Each step your facility is taking to prevent the recurrence of similar violations.

Your response should be submitted to: Food and Drug Administration, 900 Madison Avenue, Baltimore, Maryland, 21201, to the attention of Ms. Anita Richardson, Director, Compliance Branch.

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you may have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715), or through the Internet at http://www.fda.gov.

If you have technical questions about mammography facility requirements, or about the content of this letter, please feel free to contact Elizabeth A. Laudig at (410) 962-3591, extension 159.

Sincerely,

Lee Bowers
Director, Baltimore District